REMARKS

The present application relates to methods for detecting a mammalian byproduct contaminant, by detecting a mammalian troponin molecule from at least two mammalian species, and for distinguishing between a mammalian troponin molecule and an avian troponin molecule in animal feed. The methods include assays that employ ligands for the detection of mammalian troponin molecules.

Claims 10-13 and 15-17 are pending. In light of the following remarks, favorable consideration of the present application is respectfully requested.

Claim rejections under 35 U.S.C. §103(a)

The Office Action maintained the rejection of Claims 10-13 and 15-17 under 35 U.S.C. §103(a), as being unpatentable over Chen *et al.*, (*Meat Science* (2002) vol. 61:55-60, available online December 21, 2001); hereinafter "Chen *et al.*") in view of Sheng *et al.* (*J. Biol. Chem.* (1992) vol. 367(35):25407-13; hereinafter "Sheng *et al.*"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that the Patent Office has not established a *prima facie* case of obviousness in this case. A *prima facie* case of obviousness requires that the following criteria must be established: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations (*See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)); (2) the Patent Office must provide an apparent reason to combine the known elements in the claims (*See KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727 (2007)); and (3) there must be a reasonable expectation of success in combining the teachings of the reference(s) to arrive at the claimed invention (*See id.*). Moreover, only disclosed inherent properties can be part of an inquiry into obviousness (*See In re Rijckaert*, 9 F.2d 1531 (Fed. Cir. 1993)).

Claimed Invention

The claims are drawn to assays for detecting a mammalian troponin molecule in animal feed, including the steps of extracting proteins from the animal feed to form an animal feed

extract; reacting the animal feed extract with a ligand that is specific for **at least two mammalian** species troponin molecules and not specific for an **avian** troponin molecule for a time and under conditions sufficient to form a complex between the ligand and the mammalian troponin molecule; and detecting the complex either directly or indirectly. The ligand is an antibody produced by immunizing an animal with a peptide having an amino acid sequence of SEQ ID NO:2. The presence of the complex mammalian troponin molecule in the animal feed extract indicates the presence of a mammalian byproduct contaminant in the animal feed.

Prior Art Does Not Teach Every Claim Limitation

The Patent must establish that the prior art references, singly or in combination, teach each and every limitation of the claims. *See In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). In addition, only disclosed inherent properties can be part of an inquiry into obviousness (*See* MPEP § 2141(V), *citing In re Rijckaert*, 9 F.2d 1531 (Fed. Cir. 1993)). Here, the Patent Office has not met this requirement.

Applicants respectfully submit that the claims are directed to methods of detecting mammalian troponin molecules in an animal feed extract using an antibody that recognizes a troponin molecule from **at least two mammalian** species, but not a molecule from an avian species. The Patent Office has asserted, and applicants acknowledge that Sheng *et al.* disclose SEQ ID NO:2, a rabbit skeletal muscle troponin molecule. The Patent Office also has asserted that Chen *et al.* teach the production of antibodies by immunizing mice with a skeletal muscle troponin I. Applicants note, however, that although Chen *et al.* do teach the production of a monoclonal antibody, that monoclonal antibody is **specific** for the porcine troponin I and does not detect a troponin molecule from **at least two mammalian species,** as is required by the claims. Chen *et al.*'s monoclonal antibody does not recognize troponin molecules from any other mammalian species that were tested (See page 58, second column, first full paragraph and Figures 2 and 3). Chen *et al.*'s monoclonal antibody does not even recognize all porcine troponin molecules (See page 58, second column, first full paragraph). This specificity was intentional as the authors sought to test **species authenticity** or **origin** of meats and meat products (See page 55, first column, first full paragraph and bridging paragraph). Therefore,

they were interested in and described the production of antibodies that distinguish a **single** species. They did not teach the production of antibodies that recognized **at least two** species, and in fact, actually teach away from doing so.

Applicants' claimed methods have a very different purpose. Applicants have provided assays to detect any mammalian byproduct contaminants in animal feed using an antibody that can detect **at least two** mammalian species troponin molecules. As noted previously, Example 1 of the present application provides one example of a suitable antibody for the claimed methods. That is, the MT1 antibody used in Example 1 was able to detect "several different types of mammalian troponin I proteins including those from cow and pig" (Page 20, lines 11-12). The Patent Office has maintained that the features that applicants rely on are not recited in the claims. Applicants respectfully submit that the claims require that the antibody used in the methods is "specific for a mammalian troponin molecule from **at least two mammalian species**." Therefore, the only relied upon features are recited in the claims.

The Patent Office further argued that the discovery of a previously unappreciated property or new use or function of a prior art composition does not render a claim to the old composition patentable. Applicants note that the cited cases addressed composition claims and claims directed to processes of making compositions, as opposed to methods of using compositions as claimed here. Here, even if one were to combine the teachings of Sheng *et al.* with the teachings of Chen *et al.*, one would not arrive at the claimed methods. In fact, one would not even arrive at one component that is used in the claimed methods. As discussed above, Chen *et al.* teach the production of an antibody that is **species specific**. Therefore, if one of ordinary skill in the art were to produce an antibody according to the teaching of Chen *et al.* using the peptide disclosed by Sheng *et al.*, then they would produce a monoclonal antibody that is **species specific** to the rabbit troponin molecule. In addition, applicants respectfully submit that they are not even claiming a composition comprising an antibody that recognizes at least two mammalian species. Rather, they are claiming a method in which mammalian byproduct contaminants (in the form of mammalian troponin molecules) are detected in an animal feed extract, using antibodies that recognize a troponin molecule from at least two mammalian species. As discussed above, Chen *et al.* were trying to develop tests for **species authenticity** of heat-processed meats and meat products. Sheng *et al.* simply teach the isolation and sequencing

of the rabbit skeletal muscle troponin cDNA. Neither Chen *et al.* nor Sheng *et al.* teach or remotely suggest methods for detecting mammalian byproduct contaminants in an animal feed extract.

Moreover, only disclosed inherent properties can be part of an **obviousness** inquiry (*See* MPEP § 2141(V), *citing In re Rijckaert*, 9 F.2d 1531 (Fed. Cir. 1993)). This is different than a **novelty** inquiry, where it is not required that a person of ordinary skill in the art would have recognized the inherent disclosure at the time. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency]." *In re Rijckaert*, 9 F.2d 1531 (Fed. Cir. 1993), *citing In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981)(citations omitted); *see also In re Spormann*, 363 F.2d 444, 448 ("That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."); *In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989)(finding that a retrospective view of inherency does not substitute for a teaching or suggestion in an obviousness rejection). Here, the Patent Office asserted that the discovery of a previously unappreciated property or new use or function of a prior art composition does not render a claim to the old composition patentable. Such an assertion is proper in the context of a novelty inquiry, rather than an obviousness inquiry. The mere fact that it is *possible* to use the sequence disclosed by Sheng et al. to produce a monoclonal antibody that recognizes at least two mammalian species is not sufficient to render obvious the claimed methods (or even the antibodies used in the claimed methods). In addition, as noted above, Chen *et al.* teach away from producing antibodies that recognize at least two species because such antibodies would not be suitable for their purpose.

There is Not a Reasonable Expectation of Success in Arriving at the Claimed Methods

Even if the cited references did contain each of the claim limitations, there is not a reasonable expectation of success in arriving at the claimed methods if one combines the teachings of Chen *et al.* with the teachings of Sheng *et al.* As discussed in detail above, Chen *et al.* teach the production of a monoclonal antibody that is **specific** for the porcine troponin I. Chen *et al.*'s monoclonal antibody does not recognize troponin molecules from any other mammalian species that were tested, or even other porcine troponin molecules. This specificity was intentional as the authors sought to test **species authenticity** or **origin** of meats

and meat products. By contrast, Sheng *et al.* teach that the TnI sequences from rabbit, mouse, and chicken are highly homologous at the amino acid level. Therefore, applicants respectfully submit that based on the teachings of Chen *et al*, one of ordinary skill in the art only would have been motivated to produce antibodies from the portions of the rabbit TnI protein that *differed* from the mouse and chicken proteins in order to produce an antibody with the desired *species specificity*. Such an antibody would not be useful in the presently claimed methods because it would identify only one potential type of mammalian byproduct.

For at least the above reasons, applicants respectfully submit that the claims as amended are not obvious over the teachings of Chen *et al.* and Sheng *et al.* Accordingly, applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

Applicants submit that the foregoing is a full and complete Response to the Final Office Action mailed March 9, 2010. Applicants respectfully submit that the claims are in condition for allowance, and such action is courteously solicited.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 541-6662 or to Ms. Jamie Greene at (404) 745-2473 is respectfully solicited.

Applicants have submitted herewith a request for a three month extension of time, along with the appropriate fee therefore. Applicants also have submitted herewith a request for continued examination of this case, along with the appropriate fee therefore. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account Number 11-0855.

Respectfully submitted,

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